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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

5828US BX2009T01740 (3712044-00440)

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Application Number

10/624,150

Filed

July 17, 2003

First Named Inventor

Robert W. Childers, et al.

Art Unit

3767

Examiner

Laura C. Schell

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

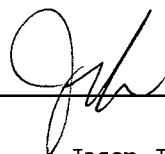
I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 65,774

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____



Signature

Jason J. Novak

Typed or printed name

312-558-5069

Telephone number

October 22, 2010

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Robert W. Childers, et al.
Appl. No.: 10/624,150
Conf. No.: 5656
Filed: July 17, 2003
Title: SYSTEM AND METHOD FOR PERFORMING PERITONEAL DIALYSIS
Art Unit: 3767
Examiner: Laura C. Schell
Docket No.: 5828US BX2009T01740 (3712044-00440)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Examiner:

Introduction

This Request and following remarks are in response to the interpretation of the prior art and the misapplication of the law of obviousness in the final Office Action dated July 22, 2010. Applicants respectfully submit that such interpretation and application rise to the level of clear error, making this case proper for pre-appeal review. The Request is filed contemporaneously with form PTO/SB/33, "Pre-Appeal Brief Request for Review" and form PTO/SB/31, "Notice of Appeal." Please charge Deposit Account No. 02-1818 for the Notice of Appeal fee set forth under 37 C.F.R. §41.20(b)(1) and any other fees connected to the request.

Claims 1 to 30 are pending in the application. In the Office Action, Claims 1 to 30 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,666,842 to Sakai ("*Sakai*") in view of "Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration," by Martin Roberts et al. ("*Roberts*"). Applicants respectfully submit that Claims 1 to 30 are not obvious in view of the present combination of references cited in the final Office Action.

Section 103 rejection of Claims 1 to 12 and 24 to 30

Regarding the rejection of Claims 1 to 12 and 24 to 30, Applicants respectfully submit that the combination of *Sakai* and *Roberts* fails to disclose or suggest a system for providing peritoneal dialysis to a patient, the system comprising a fluid circuit/loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient at an outflow rate from the

peritoneal cavity greater than an inflow rate to the peritoneal cavity, and a cyclor configured to drain dialysate at a discharge rate substantially/approximately equal to a difference between the outflow rate and the inflow rate, effective to circulate the dialysate a plurality of times along the fluid loop prior to discharge as recited, in part, by independent Claims 1 and 24.

In support of the obviousness rejection, the final Office Action cited page 377, column 1, second paragraph of *Roberts*, which discusses an alternative flow-through method that involves the use of fresh dialysate for inflow, while fluid in the patient's peritoneum is recirculated at a high flow rate. No value for the *high* flow rate is specified in the cited paragraph of *Roberts*, but the first paragraph in column 1 of page 377 discusses recirculation rates of 100 ml/min or 200 ml/min. Page 377, column 1, second paragraph of *Roberts* does however indicate that an inflow flow rate (feed rate of fresh fluid into the recirculation loop) can be 30 ml/min. *Most importantly*, the passage says, "the outflow of the spent peritoneal dialysate would be adjusted to the inflow." Applicants submit that this statement means that the outflow (discharge rate) is set to *match* the inflow (feed rate). As evidence, Applicants direct the Patent Office to page 374, column 2, second paragraph (also cited in the Office Action) and Figure 7, reproduced below, of *Roberts* that shows a similar configuration to the peritoneal dialysis system described on page 377 except that the recirculation loop of Figure 7 has a hemofilter.

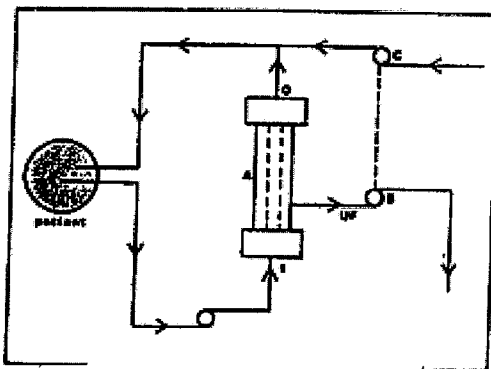


Figure 7. Flow-thru peritoneal dialysis and ultrafiltration.¹² Reprinted with permission from Kraus MA et al., Dial Transplant 12: 388, 1983.

Regarding Figure 7, page 374 of *Roberts* discloses that the recirculating rate is set at 200 ml/min. The inflow (feed rate) and outflow (discharge rate) rates are *matched* or “adjusted” to be the same, i.e., to 36 ml/min. It should be appreciated that the spent dialysate outflow of both the cited passage at page 377 of *Roberts* and Figure 7 at page 374 of *Roberts* are analogous to the

discharge fluid path of Claims 1 and 24. Since feed and discharge rates are matched, the amount of fluid introduced into the system must equal the amount of fluid discharging the system.

Roberts therefore teaches a different flow regime than that of independent Claims 1 and 24, namely, a balance of feed and discharge rates. While *Roberts* discloses matching feed and discharge rates from the fluid circuit, *Roberts* does not disclose outflow rates greater than inflow rates. *Roberts* therefore fails to disclose a fluid circuit/loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient at an outflow rate from the peritoneal cavity greater than an inflow rate to the peritoneal cavity as recited by Claims 1 and 24.

Moreover, since the feed and discharge rates of *Roberts* are matched, the inflow rate into the patient and the outflow rate from the patient must also be equal. *Roberts* therefore fails to suggest an outflow rate from the peritoneal cavity greater than an inflow rate to the peritoneal cavity as recited by Claims 1 and 24.

Roberts also fails to teach or suggest a cyclor that drains dialysate at a discharge rate substantially/approximately equal to a difference between the outflow rate and the inflow rate as recited, in part, by independent Claims 1 and 24. As discussed above, *Roberts* simply teaches a discharge rate matching a feed rate. *Roberts* however does not teach an outflow rate greater than an inflow rate and a discharge rate equal to the difference between the inflow and outflow rates.

Roberts, by contrast, relies on synchronized feed/discharge rates and inflow/outflow rates to achieve circulation. Since feed and discharge rates are equal, inflow rate must equal outflow rate to define a circulation rate. *Roberts* thus teaches a completely different flow scheme. Contrary to what the Examiner asserts, therefore, altering the flow rates in *Roberts*' system to match those of the claims would not have been obvious to one of ordinary skill in the art.

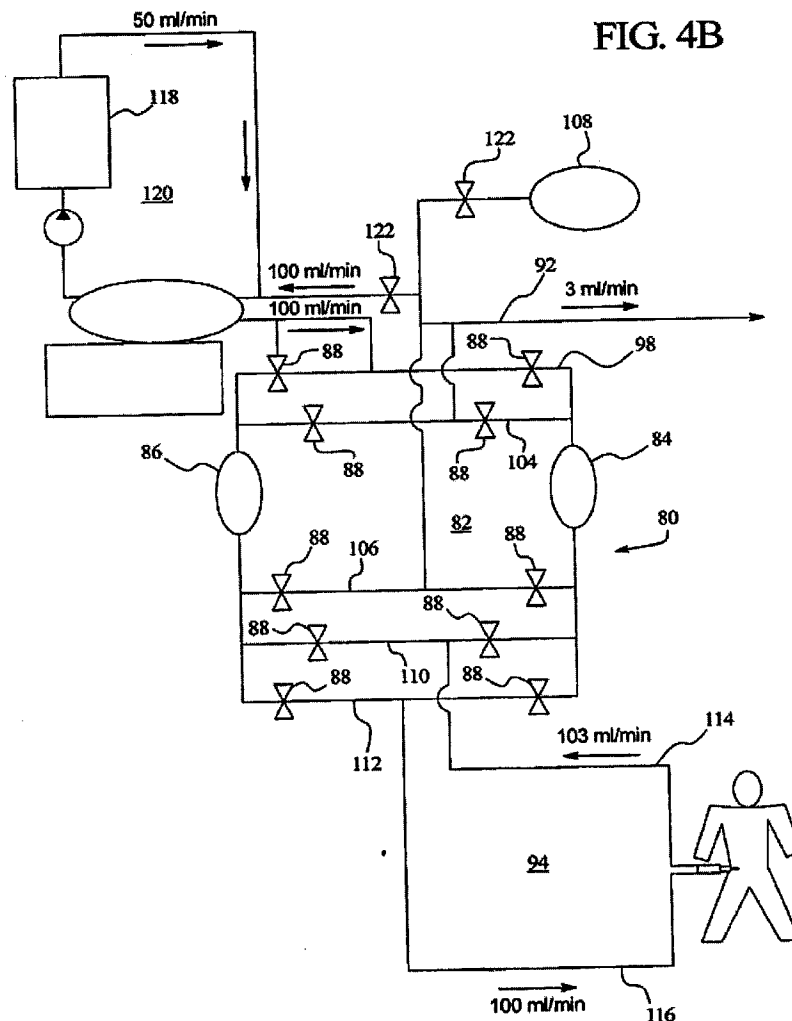
Applicants accordingly submit that Claims 1 to 12 and 24 to 30 are patentably distinguished over the combination of *Sakai* and *Roberts*, and the Examiner's rejection rises to the level of clear error.

Section 103 rejection of Claims 13 to 23

Regarding Claims 13 to 23, Applicants submit that *Sakai* and *Roberts* together fail to teach or suggest a fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity via only a single loop of the fluid loop, the fluid loop including a first fluid line in communication with a dialysate supply, a second fluid line in communication with a discharge

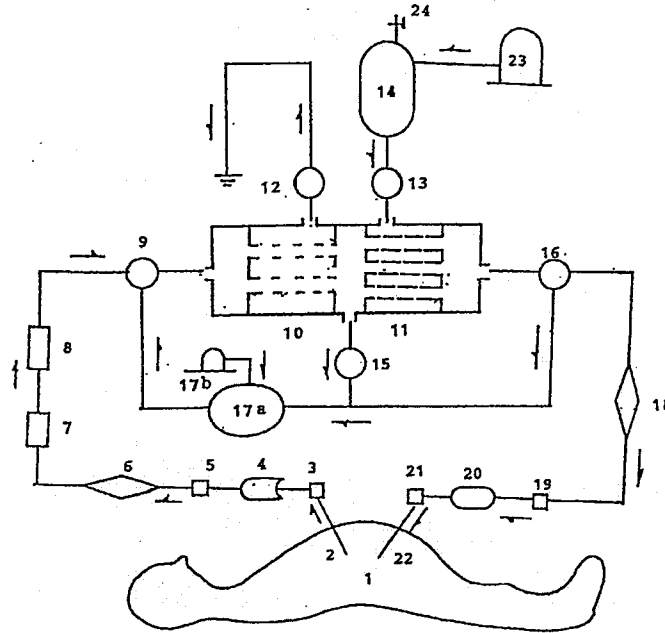
fluid path, a third line in communication with an outflow fluid path from the peritoneal cavity, and a fourth fluid line in communication with an inflow fluid path to the peritoneal cavity.

To support the obviousness rejection, the Patent Office relies on *Sakai* to teach the multi-line fluid circuit of independent Claim 13. Applicants submit however that *Sakai's* system is fundamentally different than that of Claim 13. Claim 13, in essence, recites an outflow fluid path, inflow fluid path, a discharge fluid path and a dialysate supply, with a multi-line fluid circuit in communication with each of these elements. Applicants' FIG. 4B, for example, illustrates a circulation loop 94 made up of inflow and outflow paths 114 and 116. Circulation loop 94, and associated paths 114/116, is independent of the multi-line fluid circuit 82 that includes the fluid lines communicating with the inflow, outflow, discharge and supply paths.



Sakai, on the other hand, simply teaches a fluid loop with a discharge line, a supply line, and outflow and inflow fluid paths separated by a two-part filter (see FIG. 1 below). *Sakai*

teaches a fluid loop connected to a patient 1 via inflow and outflow catheters 2/22. The fluid loop includes an outflow path from the outflow catheter 2, through heater 6 and pre-filters 7/8, to filters 10/11. Inflow path leads from filters 10/11, to warmer 18, to inflow catheter 2. Discharge path (through pump 12) and supply path (through pump 13) are coupled to filters 10/11.



Sakai fails to teach either a third line in communication with an outflow path or a fourth line in communication with an inflow path. Since *Sakai* fails to teach the multi-line fluid circuit of Claim 13, *Sakai* cannot cure the deficiencies of *Roberts*.

Applicants accordingly submit that the combination of *Sakai* and *Roberts* does not render obvious Claims 13 to 23 and that Claims 13 to 23 are patentably distinguished over the combination of *Sakai* and *Roberts*, and the Examiner's rejection rises to the level of clear error.

Respectfully submitted,

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Dated: October 22, 2010